October 31, 2004

USEPA Docket Number: OPP-2004-0159

Comments on Revised USEPA Draft Metam Sodium Risk Assessment

The following comments are submitted on behalf of the California Rural Legal Assistance Foundation (CRLAF), Farmworker Justice Fund (FJF), Natural Resources Defense Council (NRDC) and Pesticide Action Network North American (PANNA). Comments on the initial draft of this risk assessment by our respective organizations in August are hereby incorporated by reference.

Sincerely,

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Summary

As detailed below, we have reviewed the revised draft risk assessment and are encouraged to see that progress has been made in consideration of more protective endpoints and more comprehensive characterization of poisoning episodes. However, many of the concerns raised in our previous comments have not been addressed and some changes in this draft serve to exacerbate the underestimation of exposure of bystanders to MITC.

I. 159-0106 Revised Metam Sodium Exposure Assessment (August 2004)

Bystander Exposure Assessment

This revision of the risk assessment has utilized a single study for each application method to characterize off-site MOEs exceeding a level of concern at specific distances from the field. Acute and Short-term air levels with inadequate MOEs were recorded at the maximum distance monitored (1,000 feet), for both sprinkler and shank applications with standard water seals and at 274 and 300 feet respectively for sprinkler and shank applications with intermittent water seals. These results are particularly disturbing given that the industry sponsored studies chosen for sprinkler and shank standard water seal methods underestimate exposure as explained below. This draft risk assessment also fails to adequately characterize the weaknesses and limitations of these studies and fails to include a study which would better characterize exposures resulting from sprinkler applications.

Study Weaknesses and Limitations

Study 457037-01 conducted by the Metam Sodium Task Force in Kern County in summer of 1999 did not position samplers evenly around the field. Consequently, when the wind changed direction during the study there were no samplers located in a downwind direction during a significant portion of the study. For this reason, the California Department of Pesticide Regulation has concluded that MITC concentrations obtained from this study are likely to be underestimated (MITC TAC Report 2003). We agree. The CARB 1993 study should be used instead as described below.

Study 457037-02 conducted by the Metam Sodium Task Force in Kern County in the summer of 2001 only positioned samplers to the southeast and southwest of the field at 274 meters and beyond. While prevailing winds were reported to come from the north and northwest, maximum downwind MITC concentrations were not necessarily captured at 274 meters and

beyond because there was undoubtedly some fluctuation in the wind direction.

Study 457037-04 conducted by the Metam Sodium Task Force in Kern County in summer of 2001 did not position samples evenly around the field at the 500 m and 700 m distances and wind directions were not reported for this study so there is no way of ascertaining whether or not MITC concentrations were underestimated at 500 m and 700 m from the treated field. Without information on the direction of prevailing winds, the study should be rejected.

Study 457037-08 conducted by the Metam Sodium Task Force in Orange County in the Winter of 1997 was not conducted under worst case weather conditions and sampling stations at 6.1 meters and further from the field were only located to the north and northeast and wind directions were not reported so there is no way of ascertaining whether or not MITC concentrations were underestimated at and beyond 6.1 meters from the field. In the absence of wind direction information, the study should ideally be excluded. However, since it is the only drip application study available, we recommend increasing buffer zones to compensate for this weakness. Other study limitations are outlined on page 87 of 156-0106.

<u>U.S. EPA Did Not Evaluate the California Air Resources Board (CARB) Study that Provided the Best Estimate of Worst-Case Exposures</u>

U.S. EPA evaluated 12 studies to assess bystander exposures and developed exposure scenarios from these studies. We are concerned that an important monitoring study was omitted from the set of studies evaluated—the 1993 CARB study conducted in Kern County in August 1993 for an application to 20 acres using maximum application rates and sprinkler application with a water seal at summertime temperatures (downloadable at http://www.cdpr.ca.gov/docs/empm/pubs/tac/metamsod.htm, "Air monitoring for methyl isothiocyanate during a sprinkler application of metam-sodium, EH-94-02). The data collected in this study are good quality, with proper placement of samplers that enabled CARB to estimate worst-case exposure conditions for an application conducted according to currently legal label conditions. The maximum concentration observed 150 m from the field was 3,947 ug/m^3, 4.7 times higher than that of 839 ug/m^3 observed in study 457037-01. *U.S. EPA must include this study in order to cover the range of possible exposure scenarios and should utilize it as the study which best characterizes exposure from sprinkler applications.*

Ambient Air Monitoring

Table 11, which calculates MOEs from ambient air studies inappropriately, aggregates all 2001 Air Resources Board Kern air monitoring data for long term MOE calculations. The long-term MOE at the MVS site was 378. While this exceeds the EPA proposed LOC of 300, the MVS site is clearly in an area of high metam sodium use but it was not selected to be a worst case exposure site. In addition, the Level of Concern LOC of 300 for Intermediate Term (IT) exposures was exceeded at the MVS site where the MOE for ST/IT exposures was 195. Thus we conclude that this ambient data indicates that long-term ambient exposures are probably excessive in high use areas.

Bystander Exposure of Fieldworkers is Underestimated

Risk estimates still assume maximum daily 8 hour exposures for handlers and for fieldworkers working near to metam sodium treated fields. These assumptions will underestimate exposures to those handlers and field workers working 10 hour or 12 hour days. The National Agricultural Worker Survey (Mehta, K. 2000) confirms that many workers work more than 50 hours a week, hence more than 10 hours per day. In these circumstances, assuming an 8 hour day will leave many workers unprotected. Similarly, in its recent glove amendment to the Worker Protection Standard, EPA permitted the use of glove liners for 10 hours in a 24 hour period, in recognition that many workers work for 10 hours per day.

II. Revision in Hazard Identification Regulatory Endpoints

MITC Short and Intermediate term Effect Level

We think USEPA's decision to revise the MITC inhalation short and intermediate term inhalation Effect Level to a more health protective level of 5.4 ppb based predominantly on the no effects level of metaplasia of the respiratory epithelium, with consideration of nasal epithelial atrophy is moving in the right direction, though we are concerned that it utilizes a total uncertainty factor of 30 rather than 100. The use of an uncertainty factor of 100 is an established practice for the EPA and should be utilized here.
If an uncertainty factor of 100 was used the short and intermediate term inhalation effect level would be 1.6 ppb. We therefore strongly recommend that USEPA utilize an uncertainty factor of 100 or go a step further and adopt DPR's MITC seasonal effect level of 1 ppb. This effect level, approved by California's Toxic Air Contaminant Act Scientific Review Panel, is more health protective because it is based on the no effects level for

nasal epithelial atrophy and utilizes a total uncertainty factor of 300 for intra and inter-species variation (100 x as is established practice) and extrapolation from a LOAEL to a NOAEL (3x as is established practice).

Acute Inhalation Effect Level

We note that OPP has decided to adopt an acute (1-8 hour) inhalation effect level of 22 ppb which is harmonized with DPR's acute inhalation effect level. The need for a health protective acute effect level is strongly supported by the vast number of reports of eye and respiratory irritation related to bystander exposure to MITC drift.

We support the decision outlined in document 159-0116 (Memorandum: Human eye and nasal irritation resulting from air exposure to MITC) to use eye and respiratory irritation health effect endpoints. We agree that California pesticide illness data demonstrates that the general public is exposed to fumigants in air following application. This is because of the high application rates typically used for fumigants as well as fumigants' high volatility. California pesticide illness data also demonstrates that fieldworkers and other outdoor workers not involved in fumigant application are exposed as are bystanders.

We strongly support the concept expressed in 159-0116 page 3, that in the absence of more robust dose-response data from acute exposures, eye irritation can be considered as a biomarker and surrogate for potential respiratory effects.

We are, however, extremely uncomfortable with the fact that this acute (1-8 hour) inhalation effect level of 22 ppb was set based on results of a human experimental exposure study. In general we oppose the conduct of this type of study because researchers can not realistically provide adequate information for informed consent when they are doing a study to determine a NOAEL – since they don't know all the potential effects the exposure could cause. Furthermore, people with limited economic options will always have more incentive to "volunteer" for such studies. Also, such tests are often of limited scientific value in assessing risk to sensitive subpopulations, because human studies cannot ethically be conducted on the populations of greatest concern: children, infants, fetuses, and pregnant women.

However, now that this study has been conducted, we can not ethically ignore the fact that it shows a more sensitive endpoint and demonstrates the

need for a more protective acute exposure limit than the existing database of inhalation toxicology studies which are accurately characterized in this risk assessment as having "serious deficiencies" (Toxicology Chapter and document 0159-0116). As stated in document 0159-0116(page 3), "There are no studies with laboratory animals available which specifically evaluate the dose-response relationship and the continuum of potential acute, single day respiratory effects (i.e. progression to more serious clinical outcomes) from exposure to MITC."

We also concur with the conclusion expressed by USEPA in 0159-0116 that an acute inhalation neurotoxicity study in rats including pathological evaluation of the upper and lower respiratory tract is needed for MITC.

Reference:

Mehta, K., Gabbard, S. M., Barrat, V., Lewis, M., Carroll, D., & Mines, R. (2000). Findings from the National Agricultural Workers Survey (NAWS) 1997-1998: A Demographic and Employment Profile of United States Farmworkers (Research Report No. 8). Washington, DC: U.S. Department of Labor. Available at http://www.dol.gov/asp/programs/agworker/report_8.pdf.